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Evaluation of Endoscope Sheaths As Viral Barriers

Baker, Karen H. MSN; Chaput, Maria P. BS; Clavet, Clark R. MS; Varney, George W. BS; To, Theresa M. BS; Lytle, C. David PhD

From the U.S. Food and Drug Administration Center for Devices and Radiological Health (K.H.B., C.D.L.), Rockville, Maryland, and the Food and Drug Administration Winchester Engineering and Analytical Center (M.P.C., C.R.C., G.W.V., T.M.T.), Winchester, Massachusetts.

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Send Correspondence to Karen H. Baker, MSN, HFZ-470, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20852, U.S.A. E-mail: khb@cdrh.fda.gov

Objectives: Evaluate ENT endoscope sheaths as barriers to virus passage.

Study Design: "Defective" sheaths covering an endoscope were challenged with virus to determine how many virus particles could be recovered from the endoscope.

Methods: Sheaths with small laser-drilled holes (2 to 30 μm) were challenged with high-titer virus suspensions (10^8 viruses/mL). The inside of the sheath and the endoscope were separately rinsed to recover any virus that penetrated through the hole in the sheath. In an attempt to assess the possible importance of holes in the sheaths, a sequential test was conducted with an initial virus challenge outside a defective sheath (30-micron hole in the sheath), after which the possibly contaminated endoscope was removed and inserted into a second defective sheath (with a 20-micron hole at the same location) to determine whether the contaminating virus would pass outward through the second sheath.

Results: Small volumes of virus-containing fluid penetrated through the hole, e.g., 500 virus particles passed through one of three 30-μm holes. A significant fraction of those virus particles was occasionally found on the endoscope after removal from the sheath. Similar results were obtained with sheaths that had small tears (34-84 μm in length, from punctures with fine wires). Although some virus penetration could occur during the initial challenge contaminating the endoscope, no virus was detected passing outward through the second sheath.

Conclusions: Use of a sheath combined with intermediate level disinfection should provide a safe instrument for ENT endoscopy.

INTRODUCTION

Endoscopes used in ENT practice are contaminated with various types of microorganisms as they pass across the mucosa of the upper airway. If these microorganisms are not removed before subsequent use, there is a risk of disease transmission to other patients.[1] One method of decreasing this risk is the use of a sterile sheath that covers the insertion tube portion of the endoscope.[2] The U.S. Food and Drug Administration (FDA) requires manufacturers of sheaths with protective barrier claims to demonstrate this property with appropriate laboratory testing. Although viral penetration studies have been performed and accepted by the FDA as evidence of barrier effectiveness, it was unknown how small a hole would allow viral passage and how much virus could be detected through that hole.

Previously, two virus challenge methods were developed and evaluated as candidates for evaluating the barrier function of ENT endoscope sheaths.[3] One method challenged with a suspension of viruses outside the sheath. This method could reliably detect laser-drilled holes of 30-μm diameter, but not holes of 5-μm or less. The other method challenged with virus (suspended in 100 μL) inside the sheath. In this case, virus passage could be collected by submerging the sheath during pressurized endoscope insertion for laser-drilled holes 5 μm in diameter and larger. These results suggest that defective sheaths could result in viral contamination on the endoscope that could then be transmitted to patients during subsequent use of a second defective sheath.

The present study was designed to test the possibility of virus transmission through defective ENT endoscope sheaths using "defective" sheaths with laser-drilled holes in the same approximate location. The method was then extended to determine whether virus that penetrated a first defective sheath from the outside through a 30-μm hole, contaminating the endoscope, could be detected penetrating back to the outside through a second defective sheath through a 20-micron hole. The result should give an indication of the importance of holes in endoscope sheaths and the importance of cleaning, disinfecting, and/or sterilizing the endoscope between uses when single-use, disposable ENT endoscope sheaths are employed.

MATERIALS AND METHODS

Challenge Virus and Buffer

Bacteriophage φX174 served as the challenge virus. It is similar in size (27-nm diameter) to small human viruses[4] and is the standard challenge for barrier integrity tests of condoms,[5-7] gloves,[8,9] and surgical gown materials.[10] The methods of preparation and assay have been published.[11] For experiments, the virus was suspended in Dulbecco's phosphate-buffered saline (Sigma Chemical Co., St. Louis, MO), plus 0.1% Tween 80 (Sigma) to reduce surface tension (designated DPBS/T), at titers of 0.6 to 1.9 × 10^8 pfu/mL.

ENT Endoscope Sheaths

The endoscope (Olympus ENF rhino-laryngo fiberscope type P, 25-cm length, 3.4-mm diameter; Olympus Corporation of America, New Hyde Park, NY) was chosen as representative of standard adult-size flexible fiberoptic nasopharyngoscopes commonly used in ENT medical examinations. It was sterilized with ethylene oxide between experiments, courtesy of the Material Services Department, Winchester Hospital (Winchester, MA).

Commercially available sheaths made to fit the ENT endoscope were constructed from C-Flex, a highly flexible, translucent material, with a transparent, thermoplastic polyester window at the distal end. The transparent window is attached to the sheath with an ultraviolet-light-curable adhesive. For insertion and removal of the endoscope, the sheath was inflated to 7 psi. After complete insertion, the inflation pressure was released and the sheath collapsed tightly around the endoscope.

Defective sheaths were created by using excimer laser radiation (Resonetics, Nashua, NH) to produce holes of known diameters (2-4 to 30 μm) in individual sheaths at the location of maximum movement during endoscope articulation, 1.5 cm from the closed end, or by using acupuncture needles (120-300 μm diameter) (Seirin Kasei, Co. Ltd., Shimizu City, Japan) to produce small tears (32-35 μm or 81-87 μm, respectively) at the same location (Fig. 1). Of particular note, no defect noticeably affected inflation pressure of the sheath during endoscope insertion or removal. Thus a sizable hole that is not visually detectable may allow microbial contamination of the endoscope while not preventing inflation of the sheath.

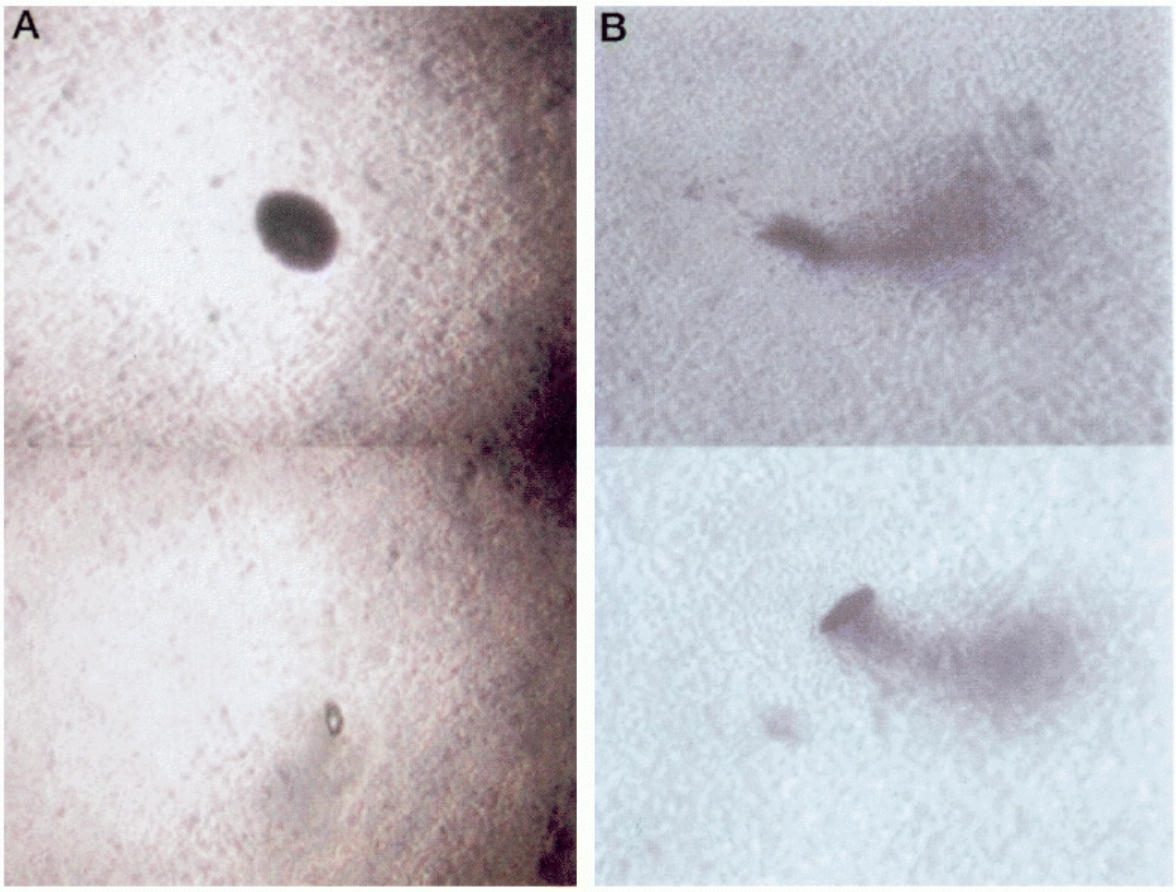

Fig. 1. Defective sheaths. **A.** Laser-drilled hole. **B.** Acupuncture needle puncture.

Virus Challenge

The endoscope sheath was challenged on the outside by submerging the lower portion of the sheathed endoscope into the challenge suspension (DPBS/T with φX174 at 0.5-1.4 × 10^8 pfu/mL)3 (Fig. 2). The endoscope was slowly articulated to one side every 5 minutes, alternating sides of articulation, and left in the completely articulated position for the remainder of each 5-minute period. After 30 minutes of submersion, the sheathed endoscope was removed from the challenge suspension and rinsed to remove any virus particles from the outside of the sheath. The endoscope was then removed from the sheath, and the endoscope and the inside of the sheath were separately rinsed to remove all viruses before virus assay.

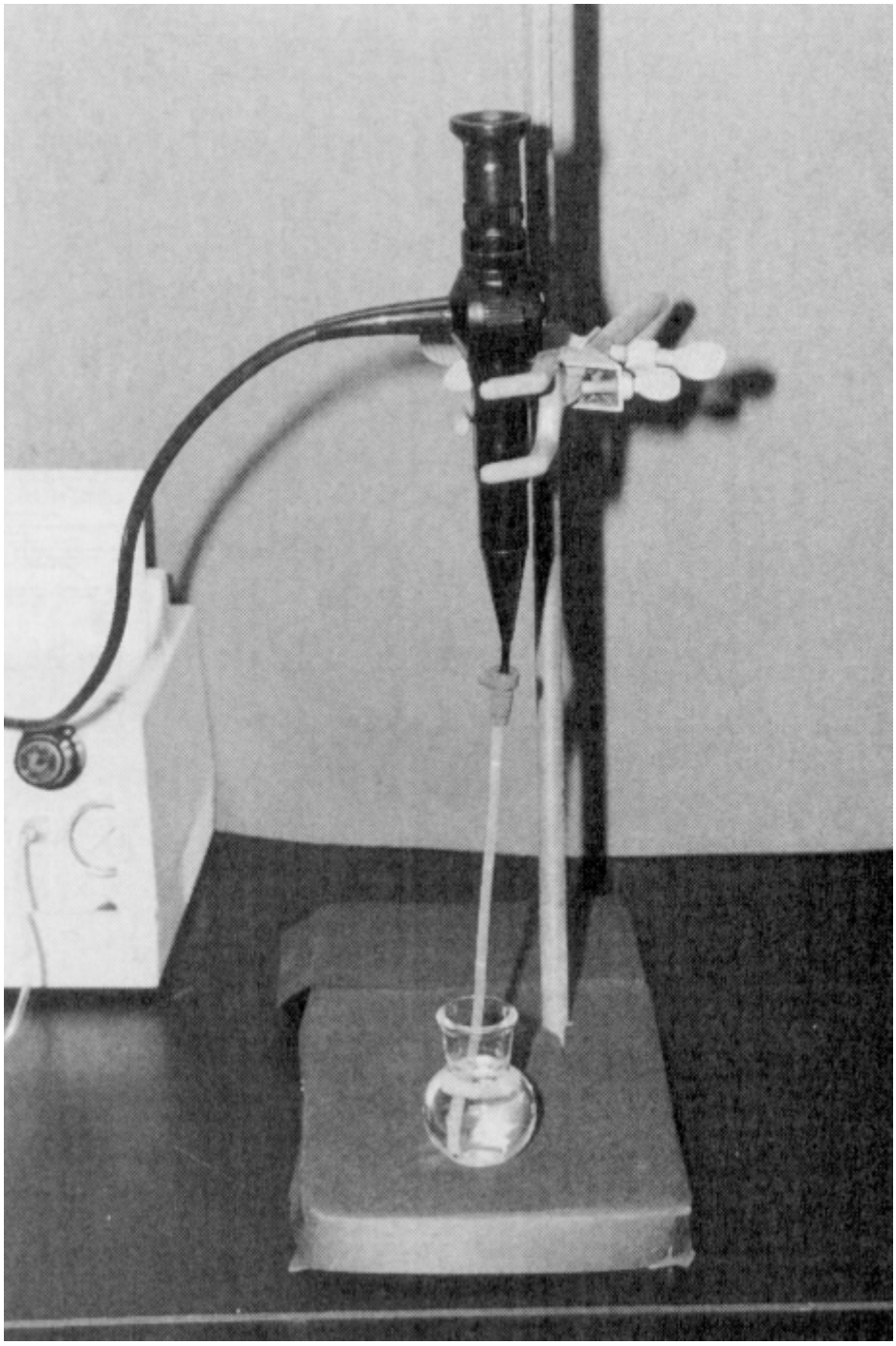

Fig. 2. General setup for the virus challenge procedures (inside of outside).

Virus Passage From Exposed Endoscope

The significance of endoscope contamination through a defective sheath might be determined by measuring virus passage from the contaminated endoscope through subsequent use with another, also defective sheath. An endoscope covered with a sheath with a 30-μm hole was exposed to a virus challenge, as described above. Next the endoscope was removed, inserted directly into a second defective sheath (with a 20-μm hole in the same approximate location), and submerged into sterile collection fluid (DPBS/T) with periodic articulation for 30 minutes. The DPBS/T served to collect any virus that passed outward through the second

defective sheath. The second sheath was partially submerged during endoscope insertion to collect any virus that might pass through the hole during the insertion process, as can happen when a larger volume (100 μL) of fluid is inside the sheath.[3] After removal of the endoscope from the second sheath, both sheaths were rinsed on the inside and the endoscope was rinsed to collect any virus for assay.

RESULTS AND DISCUSSION

Virus Challenge

The clinical situation is simulated by challenge of the sheath from the outside. With this challenge method virus passage into the sheath and onto the endoscope occurred nearly every time with 30-μm laser-drilled holes or with 84-μm tears, but not with holes of 5-μm or 33-μm tears (Table I). Intermediate-size holes gave less consistent results. The amount of passage never exceeded 500 virus particles, indicating that very little liquid transfer (0.005 μL) could provide virus passage. Snug fit of the sheath on the endoscope probably limited the passage of viruses through even relatively large defects (holes or tears). Furthermore, significant portions (up to 45%) of passed virus could be recovered from the endoscope after removal from the sheath. Thus when a very small volume (less than 0.01 μL) of virus-carrying fluid passed into the sheath, nearly half could be recovered from the endoscope after removal from the sheath.

Recovered Endoscope [Defect Size (μm)]	Recovery From		Total Recovery (pfu)	%
	Inside Sheath (pfu)	Endoscope (pfu)		
Laser-drilled holes				
2–4	<5	<5	<10	—
	<5	<5	<10	—
	<5	<5	<10	—
5	<5	<5	<10	—
	<5	<5	<10	—
	<5	<5	<10	—
10	<5	<5	<10	—
	30	5	35	14
	40	<5	40	<11
15	<5	<5	<10	—
	<5	<5	<10	—
	90	50	140	36
20	<5	<5	<10	—
	<5	<5	<10	—
	35	<5	35	<12
30	10	<5	10	<33
	45	10	55	18
	295	205	500	41
Puncture tears				
32–35†	<2	<2	<4	—
	<2	<2	<4	—
81–87‡	10	<2	10	<17
	102	84	186	45

*Challenge outside sheath: 0.6–1.9 × 10^8 pfu/mL.
†Punctured with 120-μm diameter acupuncture needle.
‡Punctured with 300-μm diameter acupuncture needle.

TABLE I. Virus Passage Through "Defects" in ENT Endoscope Sheaths Found on the Endoscope or Inside the Sheath.*

Virus Passage From Exposed Endoscope

Virus that passed through a hole in a sheath onto the endoscope surface could be passed into another sheath used subsequently (Table II). In two of three initial challenges for the defective sheaths with 30-µm holes, virus could be found inside the first sheaths at levels similar to those found earlier (compare with values in Table I). Although this finding implied that virus was present on the endoscope and could be passed into a second sheath, in only one such case was virus actually found in the second sheath. When this contamination occurred, virus was recovered from both the endoscope and inside the second sheath. In this case, approximately 9% of the virus passed into the first sheath found its way into the second. However, most important was the finding that no virus was found outside the second sheath in the collection fluid.

	After Second Submersion†		
	Recovery From		
After Initial Challenge* [Recovery From Inside First Sheath (pfu)]	Inside Second Sheath (pfu)	Endoscope (pfu)	Collection Buffer (pfu)
6.0×10^3	547	54	<1
<2	<1	<1	<1
3.5×10^2	<1	<1	<1

*Challenge titer was $1.2–1.3 \times 10^8$ pfu/mL.
†Submerged in sterile collection fluid.

TABLE II. Recovery of Virus From Sheaths and Endoscope Following Sequential Use of Two "Defective" Sheaths.

Risk Associated With Holes in Sheaths

This challenge method demonstrated that very little virus penetration can occur even with a 30-micron hole. The maximum passage was 500 virus particles when the challenge titer was 1.0×10^8 pfu/mL, indicating passage of only 0.005 µL (5×10^{-6} mL). Low titers of pathogenic viruses in clinical situations (e.g., 10^4-10^5 viruses/mL of HIV, the AIDS virus,12 would be of little concern with such low penetration. For high-titer viruses (e.g., 1011 viruses/mL of hepatitis B virus13) even these low levels of penetration would be of concern.

Recommendations for Clinical Practice

Endoscope sheaths cleared by the FDA as protective barriers (not all sheaths have been allowed this claim) have been demonstrated to be effective barriers to viral passage. Although, the manufacturers perform quality assurance testing to ensure that all sheaths are intact, there still exists the possibility of a small defect that may allow microbial passage. There are also multiple opportunities for the user to break asepsis and contaminate the endoscope directly. It is therefore recommended that a reprocessing step be combined with use of the sheath.

The data presented here indicate that the reprocessing step need not be high-level disinfection, but rather meticulous cleaning followed by intermediate-level disinfection. Intermediate-level disinfection will inactivate lipid and some nonlipid viruses, fungi, tuberculosis Mycobacterium, and most bacteria but not bacterial endospores.14 Intermediate-level disinfectants include hypochlorites, ethyl or isopropyl alcohol at 60% strength or greater, phenolics, and iodophors.15

CONCLUSION

This research supports the conclusion that proper use of an ENT endoscope sheath, meticulous cleaning of the endoscope, followed by an intermediate-level disinfection step, combined with careful aseptic technique, will provide the practitioner with an instrument that can be reprocessed in a timely manner and provide confidence that the endoscope/sheath combination is safe for patient use.

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